**King, Valerie A.**

**From:** Osborne, Kevin (PMMC Legal)
**Sent:** Wednesday, June 27, 2001 8:39 AM
**To:** Patskan, George J.
**Cc:** Solana, Rick P.; Baird, Annette M.; King, Valerie A.
**Subject:** RE: The role of this Scientific Advisory Board (SAB) is upon request of PM USA to assess the adequacy, quality, and quantity of the tests performed by Philip Morris in order to confirm the validity of the data relied on by Philip Morris to evaluate the ch

George-

As requested, I've reviewed the below for clarity and in the context of its role as an outline of professional services for the proposed contracts and have written minor questions/proposed clarifications below.. Pls. let me know if you have any questions or would like to discuss.

Val - pls. contact Bristow when you are ready to discuss contracts for all, and we can map out a plan to draft and finalize efficiently w/ Fin. , Purch. and Risk Man. I suggest that the individuals professional area(s) of expertise be described in the contract, using the areas defined below.

thanks

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# Philip Morris Product Evaluation Scientific Advisory Board

The role of this Scientific Advisory Board (SAB) is, upon request of Philip Morris USA (Philip Morris), to assess the adequacy and quality of investigations related to acceptability (i.e. a comparison to existing cigarette products) and harm reduction (i.e. the potential for a meaningful reduction in smoking-related disease) of newly developed products for adult smokers. The SAB's assessment will contribute to the validity of the data relied upon by Philip Morris to evaluate the characteristics of new products for adult smokers. Such characteristics include chemical composition, biological activity in model systems, and exposure and health effects in humans. As part of this work, the SAB may be requested to review the use of assays or procedures that deal principally with the acceptability of materials and apply to both reduced harm products and standard products alike. Additionally, the SAB may be requested to comment on the scientific aspects of studies designed principally to answer fundamental questions about smoking and health, such as a comprehensive evaluation of human exposure to smoke constituents.

To fulfill this role, the SAB will:

- review and comment on Philip Morris acceptability and harm reduction testing guidelines for the comprehensive representation of predominant standards and published concepts which are pertinent and appropriate to each respective guideline, and for accuracy and scientific soundness in applying these concepts to the evaluation (refer to "assessment" elsewhere -defer to you if meaning is different -different meaning may be inferred if use two terms) of products for adult smokers;
- evaluate study designs;
- evaluate protocols, and facilities as needed; - Does this mean only facilities, or both facilities and protocols, are evaluated? If only facilities, suggest that it read "evaluate protocols and, as considered necessary, facilities."
- periodically assess the progress and quality of the studies data by appropriate means, including on-site visits as may be useful;
- review in-progress and final test data.

In the course of its work, the SAB will receive:

- Briefings on the characteristics of products to be assessed including the chemical and physical performance properties of the new products so that an adequate review of the proposed evaluations can be conducted.



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- Briefings on proposed Philip Morris study designs and/or protocols for the determination of chemical composition and biological activity, and for human exposure and health effects studies.

- Access to testing facilities, clinical sites, analytical laboratories and other related facilities, and to all relevant test data necessary to fulfill its role.

The SAB will provide to the Philip Morris:

- written reviews and recommendations on Philip Morris's acceptability and harm reduction guidelines, study designs and/or protocols;
- periodic status reports of its reviews; (does this include review of facilities and on-site visits? I think it probably does )
- final written reports on the scientific quality and quantity of the work performed and the validity of the data, and;
- comments on the validity of the interpretation of study results and conclusions.

The Senior Management of Philip Morris Research, Development and Engineering will receive copies of written communications from the SAB and are invited to attend all SAB Meetings.

At least the following disciplines should be represented by members of the SAB:

- Toxicology/Pharmacology
- Analytical Chemistry
- Pathology
- Clinical pharmacology
- Epidemiology / Biostatistics

The SAB may recommend the use of experts in other fields (e.g. biochemistry, molecular biology or pulmonology) on a temporary basis in order to better address specific topics.

A consultant with previous experience at Philip Morris will be made available to the SAB as a subject matter expert, to assist the SAB in its understanding of cigarettes in areas such as the chemistry and toxicology of smoke.

Secretarial and technical support can be provided by Philip Morris to the SAB to assist the SAB in fulfilling its role.

-----Original Message-----
**From:** Patskan, George J.
**Sent:** Friday, June 22, 2001 12:53 PM
**To:** Osborne, Kevin (PMMC Legal)
**Cc:** Solana, Rick P.; Baird, Annette M.; King, Valerie A.
**Subject:** The role of this Scientific Advisory Board (SAB) is upon request of PM USA to assess the adequacy, quality, and quantity of the tests performed by Philip Morris in order to confirm the validity of the data relied on by Philip Morris to evaluate the chara

Kevin,

The attached file contains what I believe is the final version of the SAB charter. The changes from the version that you have previously reviewed are fairly small. As we had discussed the plan is to attach this charter to the contract of each SAB member as a means of describing, in part, the scope of the work covered by that contract. I think the other part of the scope is general consulting to PM on an individual basis if requested by PM. Valerie King has been working to put some of this together on our side; if you don't have any changes please let her know that this can be used as an attachment to the contract.

Thanks,
George



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